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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,372	12/12/2003	Robert Wood Williams III	023868.43877	2530

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EXAMINER

STANDLEY, STEVEN H

ART UNIT PAPER NUMBER

1649

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,372	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a method of determining susceptibility to toxins or Parkinson's by measuring levels of glutathione transferases, classified in class 435, subclass 7.2.
- II. Claims 26-27, drawn to a method of determining the genetic susceptibility to an environmental toxins, classified in class 424, subclass 9.1.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons:

Groups I and II are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group I is a method of determining susceptibility to environmental toxins and Parkinson's disease by first measuring glutathione transferase, then contacting with a toxin, and determining a second amount of glutathione transferase. Group II is a method of determining the genetic susceptibility to environmental toxins simply by determining the presence of genetic material that confers an increase in susceptibility. The methods have different steps, take different measurements, have different goals, and each are not required for the other. Therefore a search and examination of the methods of group I and group II would constitute an undue burden, since the searches

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are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Election of Species

2. Should applicant choose group I, a further election of species is required. This application contains claims directed to the following patentably distinct species: an assay for determining the amount of mRNA, a radioimmunoassay, an enzyme immunoassay, an immunofluorometric immuno assay, or an assay for enzymatic activity. The species are independent or distinct because they are all either different methods for measuring glutathione-s-transferase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "determining an amount of one or more glutathione-s-transferases" is generic.

3. Should applicant elect the 'assay for determining mRNA levels,' or another assay which requires the oligonucleotides below, yet a further election of species is required. This application contains claims directed to the following patentably distinct species: SEQ ID NO: 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 29, 30, 31, 33, 34, 35, 37, 38, 39, 40, 41, 42, 43, 45, 46, 47, 49, 50, 51, 53, 54, 55, 57, 58, 59, 61, 62, 63, 65, 67, 69, 70, 71. The species are independent or distinct because they are all either different oligonucleotides for measuring mRNA levels of glutathione-s-transferase.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "determining an amount of mRNA one or more glutathione-s-transferases" is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Should applicant choose group II, a further election of species is required. This application contains claims directed to the following patentably distinct species: human GSTPI (chr1: 69874218-69877056), GST mu (hGSTm4: chr1: 110677671-110687021), hGSTm2 (chr:1 10689771-110696957), hGSTm3 (chr1:1 10758175-1 10761973), hGSTm1 (chr1:110709530-110715415), or GST alpha (chr6: 52658645-52670705), hG51a2 (c16:52617245-52630341), h651a3 (chr6:52763514-52776547), or hGSTa4 (chr6:528448 14-52862163). The species are independent or distinct because they are

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all directed to unique genomic nucleic acid sequences to measure mRNA levels of glutathione-s-transferase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "determining an amount of one or more glutathione-s-transferases" is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

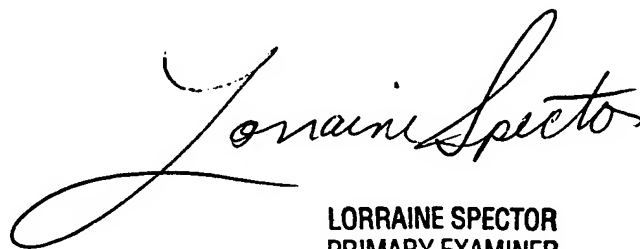
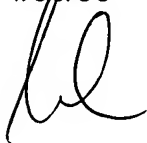
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.

4/30/06



LORRAINE SPECTOR
PRIMARY EXAMINER